Exhibit 19

Sent: Thursday, August 23, 2018 10:34 PM
To: Mathew, Lisa
Cc: ORA PHARM1 RECALLS; David Bonilla; Christopher Unger
Subject: RE: CDER Request for information

Dear Lisa
Thank you for speaking with me this afternoon to clarify what is being requested by CDER – that is:

- provide an excel spreadsheet of all valsartan API lots received that were manufactured Jan 2012 to present with the disposition of those API lots (whether still quarantined, on hold, released for further manufacture, etc.)
- If the API lot was further manufactured into finished valsartan batches what is the final disposition (e.g., recalled, on hold, still in distribution, etc.)
- These requests include both expired and un-expired API and finished products

Per our conversation, I am letting you know via email that it will take us some time to gather and collate the data. This is because of extenuating circumstances: the manufacturing site (Malta) is closed/ no longer operating, some personnel providing information are located in Europe so there are time differences, multiple ERP systems and sites that need to be queried and involved (bulk manufactured ex-US – Malta and packaged in US – Actavis Laboratories Florida (a Teva company).

Also per our conversation, we will keep you apprised of our progress in pulling the entire data together (rather than providing as data is retrieved

---

From: Mathew, Lisa [mailto:Lisa.Mathew@fda.hhs.gov]
Sent: Tuesday, August 21, 2018 5:19 PM
To: Constance Truemper
Cc: ORA PHARM1 RECALLS
Subject: CDER Request for information

Dear Connie,

I hope you are doing well.

To better ascertain what (if anything) remains in the US market made using Process IIA, CDER is requesting that your firm provide an excel spreadsheet of all valsartan API lots received

- That were made by Zhejiang Huahai Pharmaceutical Co., Ltd and the disposition of those API lots (whether still quarantined, on hold, released for further manufacture, etc.)
- If the API lot was further manufactured into finished valsartan batches what is the final disposition (e.g., recalled, on hold, still in distribution, etc.)

Please provide this information as soon as possible.

Thank you,

Lisa Mathew
Recall Coordinator

Division of Pharmaceutical Quality Operations I & IV
Office of Regulatory Affairs
U.S. Food and Drug Administration

T: 973-331-4917
F: 973-331-4969

Division of Pharmaceutical Quality Operations I: CT; DC; DE; MA; MD; ME; NH; NJ; NY; PA; RI; VA; VT; WV

orapharm1recalls@fda.hhs.gov

Division of Pharmaceutical Quality Operations IV: AK; AZ; CA; CO; HI; ID; MT; NM; NV; OR; UT; WA; WY

orapharm4recalls@fda.hhs.gov